REMARKS

This is intended as a full and complete response to the Office Action in the above-identified application dated February 12, 2003. Reexamination and reconsideration of the application is respectfully requested.

Claims 1-2, 8 and 13-29 are pending in the application. Claims 2-6 and 8-19 are cancelled. Claims 30-35 have been added. Minor amendments have been made to claims 23-24 and 26-29 to correct typographical errors. Claims 21-22 and 26-27 have been amended to recite the generic name pioglitazone.

The Examiner allowed claims 8 and 13-19. The Examiner also indicated that claim 2 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112, ¶ 1, and to include all of the limitations of claim 1. Allowed claims 8 and 13-19 and allowable claim 2 have been cancelled from the present application but will be presented in a continuation application.

Claims 1-2, 7 and 20-29 stand rejected. However, it is believed that this rejection has been overcome with the present response. Independent claims 1, 20 and 25 have been amended to clarify the species to which they are directed. It is to be understood, however, that the focus of such claims on certain compounds is solely for purposes of the interference and not a relinquishment of broader claim coverage.

Support for compounds set forth in claims 21-24 and 26-29 was identified in the prior amendments dated April 13, 2000 and November 22, 2000, respectively. The compounds ciglitazone and englitazone also find support in U.S. Patent No. 5,478,852 ('852 patent). Accordingly, support in the '852 patent for compounds identified in independent claims 1, 20 and 25 exists as follows: troglitazone (col. 14, lines 60-62), ciglitazone (col. 15, lines 8-9), pioglitazone (col. 15, lines 14-15), 5-[4-[2-[N-methyl-N-(2-pyridyl)amino]ethoxy]benzyl]

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thiazolidine-2,4-dione (col. 15, lines 28-29), and englitazone (col. 15, lines 16-17). The pharmaceutically acceptable salts of the claimed compounds are identified at column 15, line 38 - column 16, line 28 of the '852 patent. The '852 patent is cited on page 7, lines 12, 16 and 19, and incorporated by reference at page 11, lines 24-25, of the present application. Accordingly, no new matter has been added.

NEW MATTER REJECTION

The Examiner objected to the amendment filed November 22, 2000 under 35 U.S.C. § 132 on the grounds that it allegedly introduces new matter into the disclosure. The Examiner is apparently referring to the inclusion of the phrase "with the proviso that said agent is not insulin-like growth factor or dopamine agonist" in claim 1. However, the use of a negative limitation is acceptable and not new matter when alternative elements are positively recited in the specification. MPEP § 2173.05(i) (8th ed., 2001). In the present application, many alternative agents have been cited in addition to insulin-like growth factor and a dopamine agonist. Nevertheless, it is believed that this objection has been rendered moot with the present amendment. To the extent the Examiner's new matter objection is based on the inclusion of particular compounds incorporated by reference, such compounds do not constitute new matter. MPEP § 608.01(p)I. Accordingly, it is believed that the Examiner's objection under 35 U.S.C. § 132 has been overcome.

REJECTION UNDER 35 U.S.C. § 112

The Examiner rejected claims 1-2 and 7 under 35 U.S.C. § 112, ¶ 1, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection appears to be

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directed to the negative limitation included in claims 1 and 2, which has been overcome as set forth hereinabove. The rejection of claim 7 under 35 U.S.C. § 112, ¶ 1, appears to be inappropriate as the only change made to such claim from its condition as originally filed was a change of the identification of the claim upon which it depends (i.e., from 6 to 25). Accordingly, it is believed that the rejection under 35 U.S.C. § 112 has been overcome.

REJECTION UNDER 35 U.S.C. § 102

The Examiner rejected claims 1, 20-22, and 25-27 under 35 U.S.C. § 102(b) as allegedly being anticipated by Wilkerson (U.S. Patent No. 5,326,770). The Examiner also rejected claims 1 and 20 under 35 U.S.C. § 102(b) as allegedly being anticipated by Maack et al. (WO 95/13823), Baker et al. (U.S. Patent No. 5,534,615), Wurtman (U.S. Patent No. 4,775,665) or Dubach et al. (WO 96/03087).

The Examiner's rejection of claims 1 and 20 under Maack, Baker, Wurtman or Dubach, is clearly inappropriate as the Examiner has improperly disregarded the claim limitations which the Examiner has contended do not find support in the specification. *See,* MPEP § 2143.03. Regardless of the Examiner's objection to the phrase "with the proviso that said agent is not insulin-like growth factor or dopamine agonist," such phrase should have been considered and would negate an anticipation rejection. In addition, although the Examiner references Dubach et al., no basis for such rejection is provided by the Examiner. In any event, it is believed that the rejection of claims 1 and 20 on the basis of such references has been overcome in view of the present amendment.

It is also believed that the rejection of claims 1, 20-22 and 25-27 on the basis of Wilkerson has been overcome. Independent claims 1, 20 and 25 recite the administration of certain species of thiazolidinedione for the treatment of Alzheimer's disease (claims 1 and 25) or

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improving mentation of a patient with Alzheimer's disease (claim 20). Wilkerson discloses a generic formula encompassing a vast number of possible species, as well as certain preferred species within such broad generic formula. None of such preferred species are the same as any of the compounds claimed by Applicants. Anticipation is therefore negated. *See*, MPEP § 2131.02. Further, Wilkerson's reference to pioglitazone and ciglitazone appears in the BACKGROUND OF THE INVENTION along with the statement that "None of these references teach or suggest the compounds . . . are useful for treating memory disorders" Col. 4, lines 17-19. As such, Wilkerson does not teach the use of pioglitazone or ciglitazone, or any of the other claimed thiazolidinedione species, for use in connection with the treatment or improved mentation of a patient with Alzheimer's disease. Accordingly, it is believed that the rejection under 35 U.S.C. § 102 has been overcome.

REJECTION UNDER 35 U.S.C. § 103

The Examiner rejected claims 7, 23-24, and 28-29 under 35 U.S. C. § 103(a) as allegedly being unpatentable over Wilkerson in view of Olefsky (U.S. Patent No. 5,478,852). Olefsky teaches a number of compounds and is specifically incorporated by reference into the present application (*see* page 7, lines 8-19 and page 11, lines 24-25).

The Examiner has simply failed to establish a *prima facie* case of obviousness. There is no suggestion or motivation to combine Wilkerson, having a broad formula and covering a large number of possible species, with the particular species identified in Olefsky. Nothwithstanding such expansive generic formula, Wilkerson's distinction over the pioglitazone and ciglitazone references (col. 4, lines 17-19), combined with the fact that none of Wilkerson's 38 "certain 5-substituted 2,4-thiazolidinediones" (col. 4, lines 22-24) are the same as any of the claimed compounds, establishes that Wilkerson *teaches away from* the claimed invention. Such teaching

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away from pioglitazone is thus also a teaching away from what the Examiner refers to as "its functionally equivalent species" as disclosed in Olefsky. Accordingly, it is believed that the rejection under 35 U.S.C. § 103 has been overcome.

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Applicants continue to request an interference between the present application and U.S. Patent No. 6,191,154 B1. The claims of this application define the same patentable invention as claims 1-9 of U.S. Patent No. 6,191,154 B1. The interference count should correspond to claim 1 of this application, and all claims of this application and claims 1-9 of U.S. Patent No. 6,191,154 B1 should be designated as corresponding to the count.

A Fourth Supplemental Information Disclosure Statement is filed herewith.

Please grant any extensions of time required to enter this response and charge any additional required fees, including for the Fourth Supplemental Information Disclosure Statement, to Deposit Account No. 06-0916.

Respectfully submitted,

Dated: August 11, 2003

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Date **August 11, 2003** Signed: _____
Linda Phillips